AMENDED IN SENATE APRIL 21, 2003

SENATE BILL No. 771

Introduced by Senator Ortiz

February 21, 2003

An act to amend and renumber Sections 125115, 125116, and 125117 of, to add ~~Sections 125305 and 125310~~ *Section 125305* to, to add the headings of Part 5.5 (commencing with Section 125300) and Chapter 1 (commencing with Section 125300) to Division 106 of, to add Chapter 2 (commencing with Section 125330) to Part 5.5 of Division 106 of, and to repeal the heading of Article 5 (commencing with Section 125115) of *Chapter 1 of* Part 5 of Division 106 of, the Health and Safety Code, relating to human tissue.

LEGISLATIVE COUNSEL'S DIGEST

SB 771, as amended, Ortiz. Human cells: ~~stem cell research~~ *embryo registry*: egg cell donation.

Existing law declares the policy of the state that research involving the derivation and use of human embryonic stem cells, human embryonic germ cells, and human adult stem cells from any source, including somatic cell nuclear transplantation, shall be permitted, as specified. Existing law authorizes the donation of a human embryo pursuant to specific requirements and prohibits the purchase or sale of embryonic or cadaveric fetal tissue for research purposes.

This bill would require the State Department of Health Services to establish and ~~administer a stem cell research program, which among other things, would serve as a repository of embryos donated for research. The bill would create the Stem Cell Research Fund in the State Treasury. Moneys in the fund would be available for expenditure by the department for purposes of the program upon appropriation by the~~

~~Legislature~~ *maintain an anonymous registry of embryos that would provide researchers with access to embryos that are available for research purposes*.

Existing law requires a physician and surgeon or other health care provider delivering fertility treatment to provide to his or her patient designated information regarding the disposition of any human embryos remaining after the fertility treatment and requires the individual electing to donate embryos to provide written consent.

This bill would make the failure to provide information pursuant to the above requirement unprofessional conduct. *This bill would specify requirements for obtaining informed consent from any individual considering donating embryos for research. This bill would require a physician and surgeon or other health care provider to provide a form that sets forth advanced written directives regarding the disposition of embryos in specified circumstances.*

This bill also would require, on and after January 1, 2005, a physician and surgeon, prior to providing assisted egg cell, also known as ''oocyte,'' production, to provide to his or her patient a standardized written summary that would be developed by the department, as specified, of health and consumer issues relating to egg cell donation. The bill would require the physician and surgeon to obtain written consent from the prospective donor and would make it unprofessional conduct to fail to provide the summary or obtain written consent.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. The heading of Article 5 (commencing with ~~Section 125115) of Part 5 of Division 106 of the Health and Safety Code is repealed.~~ *Section 125115) of Chapter 1 of Part 5 of Division 106 of the Health and Safety Code is repealed.*

~~Article 5. Stem Cell Research~~

SEC. 2. Section 125115 of the Health and Safety Code is amended and renumbered to read:

125300. The policy of the State of California shall be as follows:

(a) That research involving the derivation and use of human embryonic stem cells, human embryonic germ cells, and human adult stem cells from any source, including somatic cell nuclear transplantation, shall be permitted and that full consideration of the ethical and medical implications of this research be given.

(b) That research involving the derivation and use of human embryonic stem cells, human embryonic germ cells, and human adult stem cells, including somatic cell nuclear transplantation, shall be reviewed by an approved institutional review board.

SEC. 3. Section 125116 of the Health and Safety Code is amended and renumbered to read:

125315. (a) A physician and surgeon or other health care provider delivering fertility treatment shall provide his or her patient with timely, relevant, and appropriate information to allow the individual to make an informed and voluntary choice regarding the disposition of any human embryos remaining following the fertility treatment. The failure to provide to a patient this information constitutes unprofessional conduct within the meaning of Chapter 5 (commencing with Section 2000) of Division 2 of the Business and Professions Code.

(b) Any individual to whom information is provided pursuant to subdivision (a) shall be presented with the option of storing any unused embryos, donating them to another individual, discarding the embryos, or donating the remaining embryos for research. *When providing fertility treatment, a physician and surgeon or other health care provider shall provide a form to the male and female partner, or the individual without a partner, as applicable, that sets forth advanced written directives regarding the disposition of embryos. This form shall indicate the time limit on storage of the embryos at the clinic or storage facility and shall provide, at a minimum, the following choices for disposition of the embryos based on the following circumstances:*

(1) In the event of the death of either the male or female partner, the embryos shall be disposed of by one of the following actions:

(A) Made available to the living partner.

(B) Donation for research purposes.

(C) Thawed with no further action taken.

(D) Donation to another couple or individual.

(E) Other disposition that is clearly stated.

(2) In the event of the death of both partners or the death of a patient without a partner, the embryos shall be disposed of by one of the following actions:

(A) Donation for research purposes.

(B) Thawed with no further action taken.

(C) Donation to another couple or individual.

(D) Other disposition that is clearly stated.

(3) In the event of separation or divorce of the partners, the embryos shall be disposed of by one of the following actions:

(A) Made available to the female partner.

(B) Made available to the male partner.

(C) Donation for research purposes.

(D) Thawed with no further action taken.

(E) Donation to another couple or individual.

(F) Other disposition that is clearly stated.

(4) In the event of the partners' decision or a patient's decision who is without a partner, to abandon the embryos by request or a failure to pay storage fees, the embryos shall be disposed of by one of the following actions:

(A) Donation for research purposes.

(B) Thawed with no further action taken.

(C) Donation to another couple or individual.

(D) Other disposition that is clearly stated.

(c) A physician and surgeon or other health care provider delivering fertility treatment shall obtain written consent from any individual who elects to donate embryos remaining after fertility treatments for research. *For any individual considering donating the embryos for research, to obtain informed consent, the health care provider shall convey all of the following to the individual:*

(1) A statement that the early human embryos will be used to derive human pluripotent stem cells for research and that the cells may be used, at some future time, for human transplantation research.

(2) A statement that all identifiers associated with the embryos will be removed prior to the derivation of human pluripotent stem cells.

(3) A statement that donors will not receive any information about subsequent testing on the embryo or the derived human pluripotent cells.

(4) A statement that derived cells or cell lines, with all identifiers removed, may be kept for many years.

(5) Disclosure of the possibility that the donated material may have commercial potential, and a statement that the donor will not receive financial or any other benefits from any future commercial development.

(6) A statement that the human pluripotent stem cell research is not intended to provide direct medical benefit to the donor.

(7) A statement that early human embryos donated will not be transferred to a woman's uterus, will not survive the human pluripotent stem cell derivation process, and will be handled respectfully, as is appropriate for all human tissue used in research.

SEC. 4. Section 125117 of the Health and Safety Code is amended and renumbered to read:

125320. (a) A person may not knowingly, for valuable consideration, purchase or sell embryonic or cadaveric fetal tissue for research purposes pursuant to this chapter.

(b) For purposes of this section, ''valuable consideration'' does not include reasonable payment for the removal, processing, disposal, preservation, quality control, storage, transplantation, or implantation of a part.

(c) Embryonic or cadaveric fetal tissue may be donated for research purposes pursuant to this chapter.

SEC. 5. A heading is added as Part 5.5 (commencing with Section 125300) of Division 106 of the Health and Safety Code, to read:

PART 5.5. USE OF HUMAN CELLS

SEC. 6. A heading is added as Chapter 1 (commencing with Section 125300) of Part 5.5 of Division 106 of the Health and Safety Code, to read:

~~CHAPTER 1. STEM CELL RESEARCH~~

CHAPTER 1. EMBRYO REGISTRY

SEC. 7. Section 125305 is added to the Health and Safety Code, to read:

~~125305. (a) The State Department of Health Services shall establish and administer a stem cell research program pursuant to this chapter to facilitate research involving the use or derivation of stem cells in California.~~

~~(b) The department may contract with the University of California, private organizations, or public entities to administer the stem cell research program.~~

~~(c) The department shall oversee the development of all policies and procedures governing the stem cell research program. The department shall ensure that the program is administered in a manner that encourages scientific discovery and innovation and is in compliance with the requirements of this chapter and Sections 125300 and 125320. The department shall ensure that its policies and procedures encourage cooperation, participation, and information sharing among participating researchers.~~

~~(d) The stem cell research program shall serve as a repository of embryos donated for research purposes and a repository for any stem cell lines derived from these embryos or other source material. The embryos and stem cell lines shall be available to any California resident who submits a research plan that is in substantial compliance with the requirements of Section 125300 and agrees to publish his or her findings and methodology.~~

~~(e) The department may adopt regulations for the purpose of implementing this section.~~

~~SEC. 8. Section 125310 is added to the Health and Safety Code, to read:~~

~~125310. The Stem Cell Research Fund is hereby established in the State Treasury. Moneys in the fund shall be available for expenditure by the department for purposes of this chapter, upon appropriation by the Legislature. The fund shall consist of money accepted by the department from grants and donations from private entities and of public moneys transferred to the fund.~~

~~SEC. 9.~~

125305. (a) The department shall establish and maintain an anonymous registry of embryos that are available for research. The purpose of this registry is to provide researchers with access to embryos that are available for research purposes.

(b) The department may contract with the University of California, private organizations, or public entities to establish and administer the registry.

(c) This section shall be implemented only to the extent that funds for the purpose of establishing and administering the registry are received by the department from private or public sources, excluding the General Fund.

SEC. 8. Chapter 2 (commencing with Section 125330) is added to Part 5.5 of Division 106 of the Health and Safety Code, to read:

CHAPTER 2. OOCYTE OR EGG CELL DONATION

125330. The following definitions shall apply to this chapter:

(a) ''Assisted oocyte production'' or ''AOP'' means pharmaceutically induced manipulation of oocyte production through the use of injectable, also known as nonoral, stimulation drugs.

(b) ''Department'' means the State Department of Health Services.

(c) ''Egg cell donor'' or ''oocyte donor'' means an individual who voluntarily gives her egg cells to another woman for the purpose of conception or gives her egg cells to another person for the purpose of research or development of medical therapies.

(d) ''Oocyte'' means an egg cell.

125335. (a) On and after January 1, 2005, prior to providing AOP, a physician and surgeon shall provide to his or her prospective oocyte donor the standardized written summary of health and consumer issues described in subdivision (b). The failure to provide to an oocyte donor this standardized written summary constitutes unprofessional conduct within the meaning of Chapter 5 (commencing with Section 2000) of Division 2 of the Business and Professions Code.

(b) (1) No later than July 1, 2004, the department, after consultation with the appropriate national medical specialty societies, shall develop a standardized written summary in laymen's language and in several languages, as necessary, regarding health and consumer issues relating to oocyte donation. The summary shall be printed and made available by the department to physicians and surgeons. The summary shall include, but not be limited to, disclosures concerning the potential risks of oocyte donation, including the risk of decreased fertility and the risks associated with using the drugs, medications, and

hormones prescribed for ovarian stimulation during the oocyte donation process.

(2) The department shall utilize existing health and consumer guidelines for assisted reproductive technologies developed by national medical societies as the basis for the information contained within the standardized written summary.

125340. On and after January 1, 2005, prior to providing AOP, a physician and surgeon shall obtain written consent from his or her prospective oocyte donor. The failure to obtain written consent from the oocyte donor constitutes unprofessional conduct within the meaning of Chapter 5 (commencing with Section 2000) of Division 2 of the Business and Professions Code.

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